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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,155	02/20/2004	Avinash G. Thombre	PC11701B	1882

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
05/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,155	THOMBRE, AVINASH G.	
	Examiner	Art Unit	
	Aradhana Sasan	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 2 and 23 were cancelled.

2. Claims 1, 3-22, and 24-27 are being presented for examination.

Claim Objections

3. Claim 12 is objected to because of the following informalities: "psychostimulants" is mistyped as "psyhostimulants". Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Sparks et al. (US 5,354,556).

The claimed invention is a palatable, chewable, controlled release pharmaceutical composition for oral administration to a companion animal comprising a therapeutically effective amount of a pharmaceutically active agent (in controlled release multiparticulate form having coated particles with an average particle size of up to about 5000μm) and a palatability improving agent (in an amount sufficient to make the pharmaceutical composition palatable to the companion animal).

Lundy et al. (WO 98/50033) teach chewable oral tablets comprising carprofen for treating pain and inflammation in dogs. This reference discloses "a solid peroral dosage

form selected from the group consisting of delayed-release oral tablet, ... multiparticulates, ... sustained release oral tablets, ... and a chewable form in which said active ingredient is consumed along with the palatable chew, or may alternatively be delivered by leaching from the body of the chew which is not consumed, during mastication by the dog being treated ... microencapsulated formulations of the active ingredient ... may be incorporated into a tablet" (Page 14, lines 15-27). Dosage forms suitable for dogs such as tablets are disclosed, along with pharmaceutical excipients and adjuvants, which create a delayed, sustained, or controlled release of the active ingredient (Page 34, lines 4-12).

Lundy does not expressly teach the coating materials for the multiparticulate form.

Sparks teaches the coating materials for a controlled release powder comprising coated microparticles, which allow a sustained release of the active ingredient (Abstract and Col. 3, lines 15-17). Sparks teaches polymers suitable for coating including hydroxypropyl methyl cellulose, ethyl cellulose, cellulose acetate phthalate (Col. 3, lines 46-52), acrylates, methacrylates, and methacrylic polymers (Col. 4, lines 6-8).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the controlled release composition as suggested by Lundy and combine it with the coating materials suggested by Sparks and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because using the coating materials allows a sustained release of the active ingredient (Sparks, Col. 3, lines 15-17).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claims 1, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Jans et al. (US 5,824,336).

The teaching of Lundy is stated above.

Lundy does not expressly teach the palatability improving agents.

Jans teaches chewable tablets for companion animals comprising an active agent, excipients and palatability improving agents. This reference teaches compositions containing large amounts of brewer's yeast (Col. 1, lines 66-67), flavoring agents "present in an amount from 0.001% to 0.5% by weight", and meat flavors as the preferred flavoring agents (Col. 2, lines 56-60).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the controlled release composition as suggested by Lundy and combine it with the flavoring and palatability improving agents suggested by Jans and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because using the flavoring and palatability improving agents enhances palatability and consequently acceptance of the composition (including the active ingredient) by the companion animal.

7. Claims 1, 18-22, 24-27are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundy et al. (WO 98/50033), in view of Sparks et al. (US 5,354,556), and further in view of Jans et al. (US 5,824,336).

Lundy does not expressly teach the coating materials for the multiparticulate form or the palatability improving agents.

The teaching of Sparks regarding the coating materials is stated above.

The teaching of Jans regarding the palatability improving agents is stated above.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the controlled release composition as suggested by Lundy and combine it with the coating materials suggested by Sparks, and the flavoring and palatability improving agents suggested by Jans, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because using the coating materials allows a sustained release of the active ingredient and using

the palatability improving agents enhances taste masking and acceptance by the companion animals.

Regarding instant claims 18 and 19, the limitation of coating percentage and palatability improving agent percentage in the composition would have been obvious to one skilled in the art because these parameters are modified during the process of routine experimentation in order to optimize the release rate and taste masking.

Regarding instant claims 20 and 21, the limitation of the active agent being an NSAID (carprofen) would have been obvious over the carprofen taught by Lundy. The coating polymers would have been obvious over Lundy, in view of the coating agents taught by Sparks, and further in view of the palatability improving agents taught by Jans.

Regarding instant claim 22, the limitation of the dosage form suitable for administration to a dog or cat would have been obvious given the peroral tablet formulations taught by Lundy (Page 14, lines 15-27), in view of the coating agents taught by Sparks, and further in view of the palatability improving agents taught by Jans.

Regarding instant claims 24-25, the process limitations for preparing the composition would have been obvious given the controlled release compositions taught by Lundy, in view of the coating polymers and process of preparing the controlled release composition taught by Sparks, further in view of the palatability improving agents taught by Jans. One skilled in the art would vary the coating on the particles, modify the taste masking or palatability improving agents in order to optimize the release rate and palatability, and form the composition into a suitable platform such as a chewable tablet to enhance acceptability by the companion animal.

Regarding instant claims 26-27, the limitations of coating percentage in the coated particles would have been obvious to one skilled in the art given the teaching of the controlled release composition by Lundy, in view of the coating materials and process taught by Sparks, and further in view of the palatability improving agents taught by Jans.

Conclusion

1. No claims are allowed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CECILIA TSANG
SUPERVISORY PATENT EXAMINER